a) the presence of at least one immunogen in the schedule for one group and not the other;
b) a difference in the size of the dose of at least one immunogen administered to both groups;
c) a difference in the number of doses of at least one immunogen administered to both groups; or
d) a difference in the day of administration, relative to birth, of the first dose of at least one immunogen administered to both groups; and

wherein the effect of the schedule on the incidence, prevalence, or frequency of the disorder is observed at least one year after the first difference in immunization between the groups is manifest, and

(II) immunizing at least one mammal with said one or more immunogens according to an immunization schedule that appears safe regarding its possible effect on the incidence , prevalence, or frequency of at least one chronic immune mediated disorder.

Please add the following new claims:

156 (new). A method for safely immunizing humans with one or more doses of one or more immunogens which induce protective immunity to one or more infectious diseases when administered according to one or more immunization schedules, said method comprising

(I) evaluating the association between said immunization schedule and one or more chronic immune mediated disorders by a) comparing the incidence, prevalence or frequency of a chronic immune mediated disorder in a group comprising humans where the majority receive an immunization schedule comprising said one or more immunogens to that in a control group comprising humans where the

majority receive a different immunization schedule, or b) comparing the risk of said chronic immune mediated disorder associated between two or more immunization schedules of said one or more immunogens where the comparisons each comprise a time span of at least one year after the administration of said one or more immunogens,

(II) determining, at least partially on the absis of said evaluation, one or more methods of immunization to allow safe immunization with said one or more immunogens , and

(III) immunizing a human against said one or more infectious diseases, with one or more immunogens by a safe immunization method identified in (II).

157 (new). The method of claim 156 in which the incidence, prevalence or frequency of at least one chronic immune-mediated disorder is compared.

158 (new). The method of claim 156 wherein said mammals are randomized in said groups.

D2 159 (new). The method of claim 157 wherein said mammals are randomized in said groups.

160 (new). The method of claim 156-159 where said comparison further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the mammal was in utero, infections during the first 12 months of life, and size of the mammal at birth, gestational age of the mammal at birth.

161 (new). The method of any one of claims 156-159 where said comparison further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens.

162 (new). The method of any one of claims 156-159 wherein the first dose of at least one immunogen in at least one of said immunization schedules is given when the mammals are less than 42 days old.

163 (new). The method of any one of claims 156-159 wherein at least one said chronic immune mediated disorder is an autoimmune disease.

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164 (new). The method of any one of claims 1-37, 44-56, 58-65, 67-96, 156-159 wherein said at least one chronic immune mediated disorder comprises diabetes.

165 (new). The method of any one of claims 156-159, where at least one chronic immune mediated disorder comprises a disorder other than diabetes.

166 (new). The method of any one of claims 156-159 wherein in said at least one immunogen is other than a live vaccine.

167 (new). The method of any one of claims 156-159 wherein said at least one immunogen is one other than a BCG immunogen or pertussis immunogen.

168 (new). The method according to any one of claims 156-159 where the vaccine is one other than a measles, mumps, rubella, BCG, or smallpox vaccine.

169 (new). The method of any one of claims 156-159 wherein said at least one immunogen is first administered to at least one

group starting after 41 days after birth but before 180 days after birth.

170 (new). The method of any one of claims 156-159 in which three or more groups, each with a different immunization schedule, are compared.

171 (new). The method of any one of claims 156-159 wherein one screened schedule provides at least one immunogen not provided by another screened schedule or fails to provide at least one immunogen provided by another screened schedule.

172 (new). The method of any one of claims 156-159 comprising comparing the risk of said chronic immune mediated disorder associated between two or more immunization schedules of said one or more immunogens.

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173 (new). The method of any one of claims 156-159 wherein mammals are excluded from a treatment group if: i) said mammals have substantial immunologic protection against the infectious disease which said immunization schedule protects against, or ii) said mammals have substantial levels of at least one surrogate marker of an autoimmune disease even if the mammals had not been previously diagnosed as having an autoimmune disease, or iii) said surrogate marker was substantially increased following a previous vaccination, infection or other immunologic challenge.

174 (new). The method of any one of claims 156-159 where said at least one additional immunogen comprises a hepatitis B immunogen.

175 (new). The method of any one of claims 156-159 where said at least one immunogen is selected from the group consisting of a diphtheria immunogen, a tetanus immunogen, a pertussis immunogen, a hemophilus influenza immunogen, a hepatitis B immunogen, a

hepatitis A immunogen, a polio immunogen, a measles immunogen, a mumps immunogen, a rubella immunogen, a varicella immunogen, a rotavirus, a pneumococcal immunogen, a neisseria immunogen, a influenza immunogen, a cholera immunogen, a typhoid immunogen, a rabies immunogen, a Lyme disease immunogen, a human papilloma immunogen, a smallpox immunogen, a anthrax immunogen, a plague immunogen, a herpes immunogen, a meningitis immunogen, an adenovirus immunogen, a cytomegalovirus immunogen, yellow fever immunogen, a hepatitis C immunogen, and an enterovirus immunogen.

176 (new). The method of any one of claims 156-159 where said at least one chronic immune-mediated disorder comprises at least one conventional organ specific autoimmune disorder and at least one rheumatic disease/connective tissue disease and at least one autoimmune cytopenia.

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177 (new). A method of immunizing a human subject which comprises: (I) screening a plurality of immunization schedules, by (a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, the first group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens according to a second screened immunization schedule, each group of mammals having been immunized according to a different immunization schedule, and (b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, by comparing the incidence, prevalence, or frequency of said chronic immune mediated disorder as a result of which at least one said screened immunization schedules may be identified as a safe immunization schedule with regard to the risk of developing

said chronic immune mediated disorder(s), (II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens is administered in accordance with said safe immunization schedule,

178 (new). The method of claim 177 where said first and second groups differ by a difference in the timing of the first dose of at least one immunogen administered to both groups.

179 (new). The method of claim 177 wherein said humans are randomized in said groups.

180 (new). The method of claim 78 wherein said humans are randomized in said groups.

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181 (new). The method of any one of claims 177-180 where said comparison further comprises consideration for at least one possible confounding variable selected from the group consisting of breast feeding, receiving antibiotics, the maternal age, family history of a chronic immune mediated disorder, maternal infections while the mammal was in utero, infections prior to the onset of said chronic immune mediated disorder, size of the mammal at birth, and gestational age of the mammal at birth.

182 (new). The method of any one of claims 177-180 where said comparison further comprises consideration for the possible confounding effect from exposure to one or more vaccine immunogens other than said one or more immunogens.

183 (new). The method of any one of claims 177-180 wherein the method is part of a production process to test vaccine lots for efficacy or safety.

184 (new). The method of any one of claims 177-180 where the

first and second groups also differ by a difference in the number of doses of at least one immunogen administered to both groups.

185 (new). The method of any one of claims 177-180 where said at least one chronic immune-mediated disorder comprises a hyperactive immune response.

186 (new). The method of any one of claims 177-180 where said at least one immunogen comprises at least one immunogen selected from the group consisting of a diphtheria immunogen, a tetanus immunogen, a pertussis immunogen, a hemophilus influenza immunogen, a hepatitis B immunogen, a hepatitis A immunogen, a polio immunogen, a measles immunogen, a mumps immunogen, a rubella immunogen, a varicella immunogen, a rotavirus, a pneumococcal immunogen, a neisseria immunogen, a influenza immunogen, a cholera immunogen, a typhoid immunogen, a rabies immunogen, a Lyme disease immunogen, a human papilloma immunogen, a smallpox immunogen, a anthrax immunogen, a plague immunogen, a herpes immunogen, a meningitis immunogen, an adenovirus immunogen, a cytomegalovirus immunogen, yellow fever immunogen, a hepatitis C immunogen, and an enterovirus immunogen.

187 (new). The method according to claims 177-180 where said (b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups, further comprises the severity of said disorder.

188 (new). The method of any one of claims 177-180 where said at least one chronic immune-mediated disorder comprises asthma.

189 (new). The method of any one of claims 1, 14, 57, 66, 77, 79, 83, 85, 86, 93, or 96, 177-180 where said at least one chronic immune-mediated disorder comprises asthma and at least one allergy.